

United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection & Quarantine
4700 River Road
Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil
Importation
Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

PERMITTEE NAME:	Jessica Giesinger	PERMIT NUMBER:	P526P-19-00016
ORGANIZATION:	Pivot Bio	APPLICATION NUMBER:	P526-181114-035
ADDRESS:	2929 7th Street Suite 120 Berkeley, CA 94710	FACILITY NUMBER:	4084
MAILING ADDRESS:	2929 7th Street Suite 120 Berkeley, CA 94710	HAND CARRY:	No
PHONE:	5152507102	DATE ISSUED:	01/03/2019
FAX:		EXPIRES:	01/03/2022
DESTINATION: DESIGNATED PORTS:	2929 7th Street, Suite 120, Berkeley, CA 94710 AZ, Nogales; CA, El Segundo; CA, Sacramento; CA, San Diego; FL, Miami (Cargo, DHL, Fed Ex, UPS, etc); FL, Orlando; GA, Atlanta; IL, Rosemont; MD, Beltsville; NJ, Linden; NY, Jamaica; TX, Humble; WA, Blaine; WA, SeaTac		

Under the conditions specified, this permit authorizes the following:

<u>Regulated Article</u>	<u>Life Stage(s)</u>	<u>Intended Use</u>	<u>Shipment Origins</u>	<u>Originally Collected</u>	<u>Culture Designation</u>
Archaea	Any	Research - Growth Chamber (lab included)	Australia, Central America, Europe, North America (except USA), South America	Originally Collected from Foreign Locations	
Bacteria	Any	Research - Growth Chamber (lab included)	Australia, Central America, Europe, North America (except USA), South America	Originally Collected from Foreign Locations	
Fungi	Any	Research - Growth Chamber (lab included)	Australia, Central America, Europe, North America (except USA), South America	Originally Collected from Foreign Locations	

SPECIAL INSTRUCTIONS TO INSPECTORS

See permit conditions below

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Osmond Baron

DATE

01/03/2019

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This permit does not authorize hand-carry or movement of the regulated material/organisms via passenger baggage into the United States.

DHS CBP INSPECTORS - SHIPMENT BY BONDED CARRIER

- 1) Confirm that the carrier of the shipment imported under this USDA PPQ 526 permit is commercially bonded.
- 2) Confirm that the imported shipment has a valid USDA PPQ Form 599 Red/White label attached to the exterior for routing to a USDA APHIS PPQ Inspection Station or other "Designated Port" as stated on the Permit. A valid label will have the permit number, expiration date, label number, and address of a USDA APHIS PPQ Plant Inspection Station/Designated Port. PLEASE NOTE: In the event of a shipment of bulk container with discrete units, a single PPQ Form 599 Red/White label may be used.
- 3) Validate the permit in ePermits using the CBP search feature.
- 4) If a valid PPQ Form 599 Red/White label is not attached to the exterior of the package or the label has been covered or is otherwise not legible, then forward to the nearest USDA APHIS PPQ Plant Inspection Station.
- 5) If the address on the airway bill does not match the address on the PPQ Form 599 Red/White label then forward the package to the nearest USDA APHIS PPQ Plant Inspection Station/designated port shown on the PPQ Form 599 label. All costs associated with rerouting misaddressed packages will be assumed by the permit holder.

APHIS PPQ INSPECTORS at PIS - Low Risk

Follow the instructions in the Plant Inspection Station Manual for Low Risk Organisms - Arthropods or Microbials Red and White Labeled Packages (may be opened outside a biosafety cabinet; see procedures for handling on page 3-7-42). For questions or concerns, contact USDA APHIS PPQ in Riverdale, MD, at 301-851-2046, toll free 866-524-5421.

PERMIT GUIDANCE

- 1) Receipt or use of foreign isolates or samples from countries under sanctions requires specific permission from the U.S. Department of Treasury; please refer to <https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx>
- 2) This permit does not authorize movement or release into the environment of genetically engineered organisms produced with the regulated organisms described in this permit. Importation, interstate movement, and environmental release of genetically engineered plant pests require a different permit issued under regulations at 7 CFR part 340. Any unauthorized interstate movement or environmental release, including accidental release, of a regulated GE organism would be a violation of those regulations. Additional guidance and contact information for APHIS Biotechnology Regulatory Services, can be found at: <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>.
- 3) If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_anproducts.shtml
- 4) If a human pathogen is identified, please refer to the CDC Etiologic Agent Import Permit Program

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at <http://www.cdc.gov/od/eaipp/>

5) This permit does not fulfill the requirements of other federal or state regulatory authorities. Please contact the appropriate agencies, such as the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, the APHIS Biotechnology Regulatory Services, or your State's Department of Agriculture to ensure proper permitting.

6) If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

PERMIT CONDITIONS

USDA-APHIS issues this permit to Jessica Giesinger of Pivot Bio in Berkeley, California. This permit authorizes the importation of the listed regulated materials/organism(s) from various researchers of the listed countries to California for laboratory and growth chamber research in the APHIS approved facility listed in the permit.

This permit authorizes Darryl Aragonés in Berkeley, California to use the regulated materials/organisms for laboratory and growth chamber research in the APHIS approved facility listed above.

1.
 - This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.
 - The permit number or a copy of the permit must accompany the shipment.
 - You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
 - You are legally responsible for complying with all permit requirements and permit conditions.
 - The regulated material and shipping container(s) are subject to inspection by officials of Custom and Border Protection (CBP) and APHIS. CBP or APHIS officials may require the shipment to be treated, seized, re-exported, or destroyed (in part or whole). You will be responsible for expenses.
 - If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
 - Without prior notice and during reasonable hours, authorized Federal and State Regulators must

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be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.


2. The permit holder must:

- maintain a valid PPQ526 permit so long as the regulated materials/organisms are alive or viable,
- not assign or transfer this permit to other persons without APHIS PPQ authorization,
- maintain an official permanent work assignment, residence, or affiliation at the address on this permit,
- notify the Pest Permit Staff as soon as possible of any change in the permit holder's work assignment, residence, or affiliation,
- notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of regulated materials/organisms,
- adequately mitigate environmental impacts resulting from unauthorized release of regulated materials/organisms and notify the Pest Permit staff immediately if one occurs,
- notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,
- destroy all regulated materials/organisms prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.

Notifications to the Pest Permit Staff must be made via 866-524-5421 or pest.permits@aphis.usda.gov within one business day of the event triggering a notification.

3. This permit does not authorize movement or use of plant pathogens listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agriculture Select Agent Services (AgSAS) immediately by phone at 301-851-3300 option 3, and within seven (7) days submit APHIS/CDC Form 4A (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, AgSAS; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at:

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https://www.selectagents.gov/resources/APHIS-CDC_Form_4_Guidance_Document.pdf). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002. Plant pathogen select agents currently listed include: *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*), *Conothyrium glycines* (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*), *Ralstonia solanacearum*, *Rathayibacter toxicus*, *Sclerophthora rayssiae*, *Synchytrium endobioticum*, and *Xanthomonas oryzae*.


4. All persons working with the listed regulated materials/organisms must be informed of these permit conditions. Anyone working with these materials/organisms must agree to and sign/initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/APHIS but must be readily accessible and made available to Federal and State regulators upon request.

Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized materials/organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

5. All persons working with the regulated material/organism must be trained on the importance of APHIS approved containment practices as described in the permit conditions and approved SOPs associated with the APHIS approved containment facility listed above.
6. APHIS authorizes the use of Chemical/Physical analysis procedures (including DNA/RNA extraction), typically authorized under a separate PPQ330 soil permit, only if the SOPs have been filed with, and approved by, the APHIS PPQ Pest Permit Staff.
7. The regulated material must be packaged in a securely closed, watertight primary container (e.g., test tube, vial, two zip-lock freezer bag, or ampule) that is completely enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container. The space between the primary and secondary containers must be made up of sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. The secondary container(s) must be enclosed in an outer shipping container constructed of corrugated fiberboard or cardboard, wood, or other material of equivalent strength.
8. After PPQ issues this 526 permit, you will need to request Red/White labels (PPQ Form 599) at least 5 days in advance of your shipping date. If you applied for your permit online using ePermits, you may request the labels using the My Shipments/Labels feature. Otherwise, send your request to Redandwhitelabelrequest@aphis.usda.gov. All email requests must come from the permit holder or designee. If requested by the designee, the permit holder must be copied on all requests. Specify the approved port as listed on the permit and the total number of labels needed. You may request additional labels the same way.

Packages without labels on the exterior may be refused entry.

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Review label instructions at:


https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/regulated-organism-and-soil-permits/ct_organisms-shipping-requirements.

You are responsible for instructing your shipper to carefully follow these instructions. You are responsible for each import shipping label issued under this permit.

9. This permit does not authorize hand carrying (baggage, personal belongings, auto, etc.). Any organisms imported by these methods will be seized and destroyed.
10.
 - Adequate protective clothing must be worn when working with soil and infected/infested samples so that movement of plant pests out of the facilities on hands, clothing, and shoes does not occur.
 - The laboratory floor must be uniform (i.e., no cracks/defects) and made of materials that can be cleaned. The floor must be maintained free of soil and infected/infested material.
 - Work benches must be uniform (i.e., no crack/defects) and made of materials that can be cleaned. When not working with the regulated material, the benches must be cleaned and maintained free of soil and infected/infested material.
 - Any sink/laboratory water that may contain live nematode life stages harbored by infested soil, infested growing media, and infected plant materials must be equipped with traps that allow collection of waste water. The waste water must be treated according to the devitalization and waste disposal condition in this permit before final disposal.
11. Upon receipt, whenever possible, all packages must be opened within a Class II or III biosafety cabinet in the approved containment facility identified above to prevent the potential dissemination of the package contents. Shipping cartons that will not fit into the biosafety cabinet may be opened outside of the cabinet. However, smaller/primary containers that hold the regulated articles must be opened within the biosafety cabinet. Cultures must be in a sealed container during transport to or within the permit holder's assigned research facilities.
12. Arthropod (If included in samples)

All samples potentially containing mobile arthropod life stages must be placed in a refrigerator for at least 4 hours upon receipt and prior to opening in the Class II biosafety cabinet. Following this initial processing, living samples in sealed containers may be removed from the biosafety cabinet for subsequent diagnostic determinations.

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13. Arthropod (If included in samples)

Arthropod specimens that are either frozen, preserved in 70 percent alcohol, or preserved in another medium (e.g. fixed in glutaraldehyde) may be moved intra- and interstate without further permitting.


14. The regulated materials/organisms listed on this permit are strictly for research in a controlled laboratory and growth chamber environment. This permit is not valid if the regulated materials/organisms will be used for plant inoculations in the greenhouse, greenhouse research, field research, or release into the environment.
15. Vector transmission is not permitted under this authorization.
16. A record of all plant pathogens and pests identified in the regulated material must be maintained at the APHIS approved containment facility identified above. These records must be available to Federal and State regulators upon request.
17. A separate continued curation PPQ 526 permit is required if the permit holder wishes to retain plant pathogens, plant pests, and biocontrol organisms isolated and identified from the regulated material for a new intended use.
18. When not working with the regulated materials/organisms, you must store and/or maintain them within the APHIS approved containment facility identified above. All stored regulated materials/organisms must be kept in a locked area with access limited to authorized personnel.
19. Standard Operating Procedures (SOPs) must be filed with, and approved by, the APHIS PPQ Pest Permit Staff at: email: pest.permits@aphis.usda.gov; phone: 866-524-5421; fax: 301-734-8700; address: 4700 River Road, Unit 133, Riverdale, MD 20737. All contact information must be kept current and the SOPs must be dated. If requirements in the permit conditions are more restrictive than the SOPs, permit conditions take precedence. APHIS PPQ must approve any changes to the SOPs before implementation.

A list of all persons with access to the containment facility must be maintained and available upon request by Federal or State Regulatory Officials.

20. Modifications to the containment facility or any changes that affect the containment of the regulated materials/organisms must be approved by APHIS prior to making changes. Please contact the Pest Permit Staff (email: pest.permits@aphis.usda.gov; phone: 866-524-5421; address: 4700 River Rd., Unit 133, Riverdale, MD 20737; Fax: 301-734-8700).
21. DEVITALIZATION AND WASTE DISPOSAL

All regulated materials/organisms and all items coming in direct contact or exposed to the regulated materials/organisms must be sterilized/sanitized/decontaminated prior to removal from the authorized containment facility. This includes all items from shipping, culturing, care, and maintenance of these regulated materials/organisms. This requirement includes but is not

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necessarily limited to: packaging directly exposed to the regulated materials/organisms, substrates (culture media, soil, plant materials (food materials or host plants)), leftover/unused/unneeded live cultures, and dead specimens/cultures unless specified otherwise in the permit.

All waste materials must be treated by one of the follow methods prior to disposal:

Use any of the following, either alone or in combination: 1) autoclaved (see protocol below), 2) disposed of off-site by a facility holding a valid PPQ compliance agreement (organisms and/or contaminated waste must be stored in sealed containers prior to pick up by this company), 3) incinerated, 4) immersed in 5,250-6,000 PPM sodium hypochlorite solution (1 part fresh household bleach to 9 parts water) for at least 20 minutes, or 5) immersed in 70 percent alcohol for at least 30 minutes.

Treated waste will be double bagged prior to disposal.

Other sterilization methods are only allowed with prior written agreement from the USDA/APHIS PPQ Pest Permit Staff.

Any equipment, supplies, tools, secondary shipping containers, packing materials (e.g. ice packs), etc. must be sterilized/sanitized/decontaminated prior to reuse, disposal, or removal from containment.

If using an autoclave the following protocol must be used:


- a. Waste must be autoclaved at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at 15 psi.
- b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
- c. The autoclave must be calibrated according to the manufacturer's instructions annually and a commercially available biological indicator kit that uses bacterial spores of *Geobacillus stearothermophilus* that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every three months.

OR

The autoclave must be calibrated according to the manufacturer's instructions every two years and a commercially available biological indicator kit that uses bacterial spores of *Geobacillus stearothermophilus* that are rendered unviable at 121 Celsius (250 Fahrenheit) must be used every two weeks.

- d. A written record of the calibration and the biological indicator tests must be maintained. You must follow the manufacturer's instructions for the *Geobacillus stearothermophilus* and if any growth is observed, you must have the autoclave serviced and retested before it is used again for the regulated articles/organisms listed on this permit.

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22. As an alternative to the DEVITALIZATION AND WASTE DISPOSAL requirements listed above, devitalization/destruction of organisms and infected material may be conducted off site by a facility holding a valid PPQ compliance agreement prior to disposal. Vendor may or may not be in the same state. All organisms, contaminants and/or packaging materials must be in sealed containers during transport to this waste management facility in order to prevent any unauthorized dissemination of the regulated articles.
23. There is to be no further movement or distribution of the listed regulated materials/organisms within the United States and its territories unless the recipient holds, or is named as a responsible party on a valid PPQ526 permit for receipt of such materials/organisms.

END OF PERMIT CONDITIONS

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